PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference NGP0025-21	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/GB 03/04099	International filing date *(day/month/year)* 25.09.2003	Priority date *(day/month/year)* 25.09.2002
International Patent Classification (IPC) or both national classification and IPC A61M5/32		
Applicant NMT GROUP PLC ET AL.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
23.04.2004	21.01.2005
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Sedy, R Telephone No. +31 70 340-2978

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB 03/04099

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-8 as originally filed

Claims, Numbers

1-17 filed with telefax on 21.12.2004

Drawings, Sheets

1/2-2/2 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

   see separate sheet

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-17
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-17
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-17
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item I
Basis of the report

According to present claim 4 it is specified that the syringe comprises a sheath. However, according to originally filed claim 5 it is specified that the needle unit comprises a sheath. Consequently, present claim 4 has been interpreted as follows: "The syringe according to claims 1, 2 or 3, wherein *the needle unit comprises* a sheath for...."

Re Item V
Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

US-B1-6 228 054 (D1) which id considered to represent the nearest **prior art** discloses (see column 8, lines 11-27 and column 9, line 65 to column 10, line 25, Figures 2,7 to 9)
a syringe (2) having a barrel, a plunger (1) and a needle unit (3), the needle unit having a housing connected to one end of the barrel, a needle-mounting hub (11), a biasing element (13) arranged to urge the hub (11) inwardly of the barrel, and a stop element (23) blocking inward movement of the hub (11) into the barrel until the hub (11) is released from the stop element (23) in response to the plunger reaching the final part of, or the conclusion of, its delivery stroke to allow retraction of the needle-mounting hub (11).

The technical problem is to prevent leakage of the syringe contents.

The solution as specified in claim 1 solves this problem by providing the syringe barrel or a part for connecting the needle housing to the barrel with a seal which is in contact with the peripheral surface of the stop element and which tends to deflect radially inwardly when a fluid with the barrel is pressurized during the delivery stroke of the plunger.
This construction improves the sealing characteristics at the needle end of the syringe.

This solution is not obvious insofar as three features are functionally interrelated, namely the lip seal, the peripheral surface of the needle housing and the plunger, which requires narrow tolerances of these parts.

Dependent claims 2-17 specify advantageous embodiments of the subject-matter of

claim 1.

Consequently, the subject-matter of claims 1 to 17 meets the requirements of Article 33(2) and (3) PCT.

CLAIMS

1. A syringe comprising a barrel (10,110), an associated plunger (11, 122) and a needle unit (12,118), said needle unit comprising a housing (14,162) connected to one end of the barrel, a needle-mounting hub (22,169), a biasing element (24,172) arranged to urge the hub inwardly of the barrel, and a stop element (34,170) blocking inward movement of the hub into the barrel until the hub is released from the stop element in response to the plunger reaching the final part of, or the conclusion of, its delivery stroke to allow retraction of the needle-mounting hub, characterized in that the barrel (10), or a part (182) for connecting the needle housing (162) to the barrel (110), is provided with a lip seal (38,179) which contacts an outer peripheral surface of the stop element (34,170) and which tends to deflect radially inwardly when a fluid within the barrel is pressurised during the delivery stroke of the plunger (11,122).

2. The syringe according to claim 1 wherein the lip seal (38,179) is integral with the barrel (10) or said connecting part (182).

3. The syringe according to claim 1 or 2 wherein the stop element (34,. 170) is arranged to snap engage with the housing (14,162) to couple the hub (22,169) to the housing and to retain the biasing element (24,172) in a stored energy condition.

4. The syringe according to claim 1, 2 or 3 including a sheath (160) for enclosing the needle (120) of the needle unit (118), the housing including one or more opening (168) through which the sheath and stop element (170) can make contact.

5. The syringe according to claim 4 wherein the stop element (170) is coupled to the needle mounting hub (169) and the sheath (160) and the stop

element can make contact so that the sheath can be used to apply axial force to the stop element without significantly stressing the coupling between the stop element and the hub.

6. The syringe according to claim 4 or 5 wherein the sheath (160) and the stop element (170) can make contact such that the sheath restricts movement of the stop element, to prevent release of the needle mounting hub from the stop element.

7. The syringe according to claim 4, 5 or 6 wherein one or more projections (176) on the stop element engage with the opening(s) (168) of the housing, the opening(s) being arranged so that one or more portions (184) of the sheath (160) can abut with one or more projections (176).

8. The syringe according to claim 7 wherein the or each of the projections (176) on the stop element engage with an inwardly directed rib (184) or the like on the housing.

9. The syringe according to claim 7 or 8 wherein the or each of the projections (176) on the stop element has an inclined outer face such that it may ride over the inner surface of the housing (162) before snap engagement with the opening(s) (168).

10. The syringe according to any one of the preceding claims wherein the plunger (11,122) is hollow and retraction of the needle-mounting hub (22,169) is into the hollow plunger.

11. The syringe according to any one of the preceding claims wherein, once the housing (14) or the connecting part (182) is connected to the barrel (10, 110), the force required to free the housing or the connecting part from the barrel is

substantially in excess of the force required to effect the connection to the barrel.

12. The syringe according to any one of the preceding claims wherein the housing (14) or the connecting part (182) is engageable with the barrel (10,110) with a snap fit.

13. The syringe according to any one of the preceding claims wherein the biasing element (24,172) is a coiled compression spring, arranged in encircling relation with the needle (30,120).

14. The syringe according to any one of the preceding claims wherein the needle mounting hub (22,169) and the stop element (34,170) are formed as plastics mouldings such that the stop element is axially captive with the hub, the stop element and the hub being disengageable from each other during said final part of, at the conclusion of, the delivery stroke of the plunger (11,122) to allow retraction of the needle-mounting hub.

15. The syringe according to any one of the preceding claims 1 to 9, or claims 11 to 14 as appendent to claims 1 to 9, wherein the plunger (11,122) comprises a piston member and a separate hollow rod.

16. The syringe according to claim 10 wherein the plunger (122) is associated, at its forward end, with a portion (136) which is severable in response to movement of the plunger over the final part of, or at the conclusion of its delivery stroke, to allow retraction of the needle mounting hub (169) into the hollow plunger.

17. The syringe according to any one of the preceding claims wherein the stop element (34,170) is of generally cylindrical configuration and comprises a forward portion (36) within the housing and a rearward portion (40) of tapering configuration.